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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,894	05/15/2007	Donna Bushell-Williams	056159-5263	3595

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,894	BUSHELL-WILLIAMS ET AL.	
	Examiner	Art Unit	
	CHRISTIAN L. FRONDA	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *9 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 May 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-8 and 10-12) in the reply filed on 06/29/2009 is acknowledged. The arguments filed have been considered but are not persuasive. Restriction is required under 35 U.S.C. 121 and 372, and the instant application contains inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. As previously stated, a same or corresponding technical feature shared among Inventions 1-3 is a fusion protein comprising a carbohydrate binding domain and a domain having a high binding affinity for a microcapsule comprised of or containing a melamine based chemical component.

However, the combination of the references of Davis et al. (WO 01/46357, published 06/28/2001; PTO 1449 of IDS filed 05/11/2006) and Uchiyama et al. (WO 03/089019, published 10/30/2003; PTO 1449 of IDS filed 05/11/2006) teaches such fusion protein. Davis et al. teaches a fusion protein comprising a carbohydrate binding domain and a domain having high binding affinity for another ligand, where the said domain includes antibodies that can be generated that are specific for almost any protein, organic molecule, or cell surface that is likely to be encountered (see entire publication and claims, especially section 1.2.1 on page 5). Davis et al. teach microcapsules having melamine as chemical component and their use as carriers of benefit agents (see entire publication). Therefore, it would have been obvious to one of ordinary skill in the art to make a fusion protein comprising a carbohydrate binding domain and an antibody having high affinity for a microcapsule comprised of or containing a melamine based chemical component by combining the teachings of Davis et al. and Uchiyama et al.

Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Inventions 1-3 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 9 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-8 and 10-12 are under consideration in this Office Action.

3. The specification is objected to for failing to supply a sequence identifier to all disclosed sequences. According to MPEP § 2422 sequences in the specification and claims must use a sequence identifier preceded by "SEQ ID NO". In particular, the Fig 5 shows nucleotide sequences without corresponding sequence identifiers. Furthermore, all the particular sequences are not present in the paper copy and computer readable copy of sequence listing. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821-1.825. Applicant must provide a substitute computer readable form (CFR) copy of the sequence listing, a substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same as required by 37 CFR 1.821-1.825.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-8 and 10-12 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, do not sufficiently distinguish over proteins as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the phrase "such as" which renders the claim vague and indefinite because it is uncertain if the claim is limited to the recited fungal or bacterial biological sources.

Claim 8 recites the phrase "preferably 2-5 amino acids" which renders the claim vague and indefinite because it is uncertain if the claim is limited to a linker consisting of 2-5 amino acids.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-8 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants are directed toward the current USPTO Written Description Training Materials made available to the public on 04/11/2008 for information regarding examination of

patent claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph.

The claims are genus claims encompassing a genus of fusion proteins comprising a genus of carbohydrate binding domains and a genus of domains having a high binding affinity for a microcapsule comprised of or containing a melamine based chemical component. The scope of each genus includes many members with widely differing amino acid sequences and structures from many biological sources, where the genus is highly variable because a significant number of structural and chemical differences between genus members exists. While the specification discloses melamine-binding proteins VhhM-1E7, VhhM-1C8, and VhhM-1G711, the specification, however, does not describe and define any structural features, amino acid sequences, and/or biological functions that are commonly possessed by members of each genus.

MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification fails to disclose additional fusion proteins. As such the disclosure of the above mentioned melamine-binding proteins VhhM-1E7, VhhM-1C8, and VhhM-1G711 is insufficient to be representative of the attributes and features common to all the members of each claimed genus.

Vas-Cath, Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class, where the specification provided only the bovine sequence.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the each claimed genus.

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

According to MPEP 2143:

> "Exemplary rationales that may support a conclusion of obviousness include:
>
> (A) Combining prior art elements according to known methods to yield predictable results;
>
> (B) Simple substitution of one known element for another to obtain predictable results;
>
> (C) Use of known technique to improve similar devices (methods, or products) in the same way;
>
> (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
>
> (E) " Obvious to try " – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
>
> (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
>
> (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.
>
> Note that the list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel."

11. Claims 1-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (WO 01/46357, published 06/28/2001; PTO 1449 of IDS filed 05/11/2006) in view of Uchiyama et al. (WO 03/089019, published 10/30/2003; PTO 1449 of IDS filed 05/11/2006) and US Patent 5,593,850 (published 01/14/1997; PTO 892).

Davis et al. teach a fusion protein comprising cellulose binding domain obtainable from *Trichoderma* and *Humicola* and a domain having high binding affinity for another ligand, where the said domain includes peptides and antibodies, such as the Heavy Chain antibody found in Camelidae (the binding domain of this antibody consists of a single polypeptide fragment which is the variable region of the heavy chain polypeptide (HC-V)), that can be generated that are specific for almost any protein, organic molecule, or cell surface that is likely to be encountered. Davis et al. teach that the cellulose binding domain is connected to the domain having a high binding affinity for another ligand by means of a linker consisting of about 0-20, preferably about 2-15, more preferably of 2-5 amino acid residues. Davis et al. teach detergent compositions comprising such fusion protein, surfactants, and benefit agents including perfumes, fragrances, polymeric lubricants, and photoprotective agents, where the detergent compositions are capable of delivering the benefit agent to a fabric during a washing or rinsing process and the fragrances or perfumes may be encapsulated in latex microcapsules or gelatine based coacervates. See entire publication and claims, especially pages 1-19.

The teachings of Davis et al. differ from the claims in that the fusion protein does not comprising a domain having binding affinity for a microcapsule comprised or containing a melamine based chemical component.

Uchiyama et al. teach malodor-controlling compositions comprising microcapsules having melamine as chemical component and their use as carriers of benefit agents including perfume and odor control agent. Uchiyama et al. teach that the malodor-controlling compositions can be applied to surfaces, such as fabrics, to reduce or remove malodor from the surface and to provide a controlled-release of the active material onto the surface or into the environment surrounding the surface. See entire publication especially pages 1-12.

US Patent 5,593,850 teaches generation of monoclonal antibodies to polymers. See entire publication.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the fusion protein of Davis et al. such that the peptide or antibody is generated to have a high binding affinity to the microcapsules of Uchiyama et al. having melamine as chemical component. One of ordinary skill in the art would be motivated to do this in order to have a fusion protein that will allow for delivery of a benefit agent such as a perfume and odor control agent to a surface such as a fabric during a washing or rinsing process and surface and provide a controlled-release of the benefit agent onto the surface or into the environment surrounding the surface. One of ordinary skill in the art has a reasonable expectation of success since Davis et al. teach the successful construction of fusion proteins comprising a carbohydrate binding domain and a domain having high binding affinity for another ligand, and US Patent 5,593,850 teaches successful generation of monoclonal antibodies to polymers.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/
Primary Examiner
Art Unit 1652